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AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions, and listings, of claims in the application.

1. (Currently Amended) A stable, sterile pharmaceutical formulation comprising lyophilized azithromycin, an acid and ethanol, wherein the ethanol is present in an amount from about ~~0.003% to about 3.0%~~ 0.005% to about 0.5% by weight of the pharmaceutical formulation.

2. (Original) The formulation of claim 1, wherein the lyophilized azithromycin is present in an amount from about 300 mg to about 700 mg.

3. (Original) The formulation of claim 2, wherein the lyophilized azithromycin is present in an amount of about 500 mg.

4. (Original) The formulation of claim 1, wherein the ethanol is present in an amount of about 0.05% by weight of the pharmaceutical formulation.

5. (Previously presented) The formulation of claim 1, wherein said acid is selected from the group consisting of citric acid monohydrate, anhydrous citric acid, sodium citrate, hydrochloric acid, lactic acid, glycolic acid, acetic acid, phosphoric acid, and tartaric acid.

6. (Original) The formulation of claim 1, wherein said formulation further comprises a base selected from the group consisting of sodium hydroxide, potassium hydroxide, calcium hydroxide, aluminum hydroxide, and zinc hydroxide.

7. (Original) The formulation of claim 1, contained within a sealed container.

8. (Original) The formulation of claim 7, wherein the container defines an opening and comprises a means for sealing the opening.

9. (Original) The formulation of claim 8, wherein the container is a glass vial.

10. (Original) The formulation of claim 8, wherein the means for sealing the opening comprises a stopper.

11. (Original) The formulation of claim 10, wherein the stopper is pierceable by a hypodermic needle or a blunt cannula.

12. (Original) The formulation of claim 10, further comprising an outer seal which covers and entirely surrounds the stopper.

13. (Original) The formulation of claim 12, wherein the outer seal comprises a lid which is manually removable, to provide access to the stopper.

[illegible] solution prepared by dissolving the formulation of claim 1 in an

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1. (Currently Amended) A stable, sterile pharmaceutical formulation comprising lyophilized azithromycin, an acid and ethanol, wherein the ethanol is present in an amount from about ~~0.003% to about 3.0%~~ 0.005% to about 0.5% by weight of the pharmaceutical formulation.

2. (Original) The formulation of claim 1, wherein the lyophilized azithromycin is present in an amount from about 300 mg to about 700 mg.

3. (Original) The formulation of claim 2, wherein the lyophilized azithromycin is present in an amount of about 500 mg.

4. (Original) The formulation of claim 1, wherein the ethanol is present in an amount of about 0.05% by weight of the pharmaceutical formulation.

5. (Previously presented) The formulation of claim 1, wherein said acid is selected from the group consisting of citric acid monohydrate, anhydrous citric acid, sodium citrate, hydrochloric acid, lactic acid, glycolic acid, acetic acid, phosphoric acid, and tartaric acid.

6. (Original) The formulation of claim 1, wherein said formulation further comprises a base selected from the group consisting of sodium hydroxide, potassium hydroxide, calcium hydroxide, aluminum hydroxide, and zinc hydroxide.

7. (Original) The formulation of claim 1, contained within a sealed container.

8. (Original) The formulation of claim 7, wherein the container defines an opening and comprises a means for sealing the opening.

9. (Original) The formulation of claim 8, wherein the container is a glass vial.

10. (Original) The formulation of claim 8, wherein the means for sealing the opening comprises a stopper.

11. (Original) The formulation of claim 10, wherein the stopper is pierceable by a hypodermic needle or a blunt cannula.

12. (Original) The formulation of claim 10, further comprising an outer seal which covers and entirely surrounds the stopper.

13. (Original) The formulation of claim 12, wherein the outer seal comprises a lid which is manually removable, to provide access to the stopper.

14. (Original) A solution prepared by dissolving the formulation of claim 1 in an aqueous vehicle.

15. (Original) The solution of claim 14, wherein the azithromycin is present in the solution in an amount of about 100 mg/mL or less.

16. (Original) A dilute solution prepared by diluting the solution of claim 15 in an aqueous vehicle.

17. (Original) The dilute solution of claim 16, wherein the azithromycin is present in the dilute solution in an amount from about 0.5 mg/mL to about 5 mg/mL.

18. (Original) The dilute solution of claim 16, wherein the azithromycin is present in the dilute solution in an amount from about 1.0 mg/mL to about 2.0 mg/mL.

19. (Currently Amended) A liquid composition comprising an ethanolate of azithromycin, citric acid, and sodium hydroxide, wherein the ethanol is present in an amount from about 0.005% to about 0.5% by weight of the composition.

20. (Original) The composition of claim 19, wherein the azithromycin is present in the composition in an amount from about 10 mg/mL to about 500 mg/mL.

21. (Original) The composition of claim 19, wherein the azithromycin is present in the composition in an amount of about 74 mg/mL or about 75 mg/mL.

22. (Currently Amended) A method of producing a stable, sterile pharmaceutical product comprising lyophilized azithromycin, an acid and ethanol, which method comprises preparing a composition comprising an ethanolate of azithromycin, and lyophilizing the

composition, wherein ethanol is present in an amount from about 0.005% to about 0.5% by weight of the composition.

23. (Currently Amended) A method of producing a stable, sterile pharmaceutical formulation comprising lyophilized azithromycin, which method comprises:

(a) preparing a liquid composition comprising an ethanolate of azithromycin and an aqueous solvent,

(b) chilling the composition to a temperature from about -10° C to about 15° C, wherein the temperature is maintained for at least about 20 minutes to about 2 hours,

(c) freezing the composition to a temperature of from about -10° C to about -70° C, to produce a frozen mixture, wherein the temperature is maintained for at least about 30 minutes to about 20 hours,

(d) subjecting the frozen mixture to a primary drying stage, which comprises applying a vacuum to reduce the pressure by an amount effective to remove aqueous solvent from the frozen mixture, and, while applying the vacuum, changing the temperature of the frozen mixture to a primary drying temperature, wherein the primary drying temperature is from about -30° C to about 20° C, and wherein the primary drying temperature is maintained for at least about 15 hours to about 50 hours, to produce a first intermediate, and

(e) subjecting the first intermediate to a secondary drying stage, which comprises applying a vacuum to reduce the pressure by an amount effective to remove aqueous solvent from the first intermediate, and, while applying the vacuum, and changing the temperature of the first intermediate to a secondary drying temperature, wherein the secondary drying temperature is from about 0° C to about 60° C, and wherein the secondary drying temperature is maintained for at least about 5 hours to about 30 hours, to produce the pharmaceutical formulation, wherein ethanol is present in an amount from about 0.005% to about 0.5% by weight of the pharmaceutical formulation.

24. (Currently Amended) A method of producing a stable, sterile pharmaceutical formulation comprising lyophilized azithromycin, which method comprises:

(a) preparing a liquid composition comprising an ethanolate of azithromycin and an aqueous solvent,

(b) chilling the composition to a temperature from about -10° C to about

15° C, wherein the temperature is maintained for at least about 20 minutes to about 2 hours,

(c) freezing the composition to a temperature of from about -10° C to about -70° C, to produce a frozen mixture, wherein the temperature is maintained for at least about 30 minutes to about 20 hours,

(d) subjecting the frozen mixture to a primary drying stage, which comprises applying a vacuum to reduce the pressure by an amount effective to remove aqueous solvent from the frozen mixture, and, while applying the vacuum, changing the temperature of the frozen mixture to a primary drying temperature, wherein the primary drying temperature is from about -30° C to about 20° C, and wherein the primary drying temperature is maintained for at least about 15 hours to about 50 hours, to produce a first intermediate, and

(e) subjecting the first intermediate to a secondary drying stage, which comprises applying a vacuum to reduce the pressure by an amount effective to remove aqueous solvent from the first intermediate, and, while applying the vacuum, (i) changing the temperature of the first intermediate to a first secondary drying temperature, wherein the first secondary drying temperature is from about 0° C to about 45° C, and wherein the first secondary drying temperature is maintained for at least about 5 hours to about 30 hours, and (ii) changing the temperature of the first intermediate to a second secondary drying temperature, wherein the second secondary drying temperature is from about 0° C to about 60° C, and wherein the second secondary drying temperature is maintained for at least about 5 hours to about 30 hours, to produce the pharmaceutical formulation, wherein ethanol is present in an amount from about 0.005% to about 0.5% by weight of the pharmaceutical formulation.

25. (Original) The method of claim 24, wherein the composition is chilled to a temperature from about 0° C to about 10° C.

26. (Original) The method of claim 24, wherein the composition is frozen to a temperature of from about -30° C to about -50° C.

27. (Original) The method of claim 26, wherein the composition is frozen to a temperature of about -40° C.

28. (Original) The method of claim 24, wherein the temperature at which the composition is frozen is held for at least about 1 hour.

29. (Original) The method of claim 24, wherein the primary drying temperature is from about 0° C to about 20° C.

30. (Original) The method of claim 29, wherein the primary drying temperature is about 8° C.

31. (Original) The method of claim 24, wherein the primary drying temperature in the primary drying stage is maintained for at least about 20 hours to about 40 hours.

32. (Original) The method of claim 31, wherein the primary drying temperature in the primary drying stage is maintained for at least about 36 hours.

33. (Original) The method of claim 24, wherein the primary drying stage is carried out at a pressure of about 200 micron Hg or less.

34. (Original) The method of claim 33, wherein the primary drying stage is carried out at a pressure of about 80 micron Hg.

35. (Original) The method of claim 24, wherein the first secondary drying temperature is from about 20° C to about 40° C.

36. (Original) The method of claim 35, wherein the first secondary drying temperature is about 35° C.

37. (Original) The method of claim 24, wherein the second secondary drying temperature is from about 30 °C to about 50° C

38. (Original) The method of claim 37, wherein the second secondary drying temperature is about 45° C.

39. (Original) The method of claim 24, wherein the temperature of the frozen mixture in the secondary drying stage is changed at a rate of about 1° C per minute or less.

40. (Original) The method of claim 39, wherein the temperature of the frozen mixture in the secondary drying stage is changed at a rate from about 0.05 to about 0.1° C per minute.

41. (Original) The method of claim 24, wherein the first secondary drying temperature in the secondary drying stage is maintained for at least about 10 hours to about 20 hours.

42. (Original) The method of claim 41, wherein the first secondary drying temperature in the secondary drying stage is maintained for at least about 15 hours.

43. (Original) The method of claim 24, wherein the second secondary drying temperature in the secondary drying stage is maintained for at least about 10 hours to about 20 hours.

44. (Original) The method of claim 43, wherein the second secondary drying temperature in the secondary drying stage is maintained for at least about 18 hours.

45. (Original) The method of claim 24, wherein the secondary drying stage is carried out at a pressure of about 200 micron Hg or less.

46. (Original) The method of claim 45, wherein the secondary drying stage is carried out at a pressure of about 80 micron Hg.

47. (Original) The method of claim 24, wherein (a) the primary drying temperature is from about 0° C to about 20° C, (b) the primary drying stage is carried out at a pressure of about 200 micron Hg or less, and (c) the primary drying temperature is maintained for at least about 20 hours to about 40 hours.

48. (Original) The method of claim 24, wherein (a) the first secondary drying temperature is from about 20° C to about 40° C, (b) the first secondary drying temperature is maintained for at least about 10 hours to about 20 hours, (c) the second secondary drying temperature is from about 30° C to about 50° C, (d) the second secondary drying temperature is maintained for at least about 10 hours to about 20 hours, (e) the secondary drying stage is carried out at a pressure of about 200 micron Hg or less, and (f) the temperature of the first intermediate in the secondary drying stage is raised at a rate of about 0.05-0.1° C per minute.

49. (Original) The method of claim 24, wherein (a) the composition is frozen to a temperature from about -30° C to about -50° C, and the temperature at which the composition is frozen is maintained for at least about 30 minutes to about 10 hours, (b) the primary drying temperature is from about 0° C to about 20° C, and the primary drying temperature is maintained for at least about 20 hours to about 40 hours, (c) the first secondary drying temperature is from about 20° C to about 40° C, and the first secondary drying temperature is maintained for at least about 10 hours to about 20 hours, (d) the second secondary drying temperature is from about 30° C to about 50° C, and the second secondary drying temperature is maintained for at least about 10 hours to about 20 hours.

50. (Original) The method of claim 24, wherein the composition is aseptically filtered and aseptically filled into a container after the completion of step (a) and before the completion of step (b).

51. (Currently Amended) A pharmaceutical dosage form comprising a sealed container and a pharmaceutical formulation comprising a therapeutically effective amount of lyophilized azithromycin, an acid and an amount of ethanol contained within the container, wherein the ethanol is present in an amount from about 0.005% to about 0.5 % ~~0.003% to about 3.0%~~ by weight of the pharmaceutical formulation.

52. (Original) The pharmaceutical dosage form of claim 51, wherein the lyophilized azithromycin is present in the sealed container in an amount from about 300 mg to about 700 mg.

53. (Original) The pharmaceutical dosage form of claim 51, wherein the lyophilized azithromycin is present in the sealed container in an amount of about 500 mg.

54. (Original) The pharmaceutical dosage form of claim 51, wherein the ethanol is present in an amount of about 0.05% by weight of the pharmaceutical formulation.

55. (Previously Presented) The pharmaceutical dosage form of claim 51, wherein said acid selected from the group consisting of citric acid monohydrate, anhydrous citric acid, sodium citrate, hydrochloric acid, lactic acid, glycolic acid, acetic acid, phosphoric acid, and tartaric acid.

56. (Original) The pharmaceutical dosage form of claim 51, which further comprises a base selected from the group consisting of sodium hydroxide, potassium hydroxide, calcium hydroxide, aluminum hydroxide, and zinc hydroxide.

57. (Original) A method of treating a disease in a patient, which method comprises dissolving the pharmaceutical formulation of claim 1 in a pharmaceutically acceptable solvent to produce a pharmaceutically acceptable solution, and administering the solution to a patient in need thereof.

58. (Original) The method of claim 57, wherein the disease is community-acquired pneumonia or pelvic inflammatory disease.

59. (Original) The method of claim 57, wherein the disease is caused by a microorganism.

60. (Original) The method of claim 59, wherein the microorganism is selected from the group consisting of *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Neisseria gonorrhoeae*, *Chlamydia pneumoniae*, *Chlamydia trachomatis*, *Legionella pneumophila*, *Mycoplasma hominis*, and *Mycoplasma pneumoniae*.

61. (Original) The method of claim 59, wherein the microorganism is selected from the group consisting of *Streptococcus agalactiae*, *Streptococcus pyogenes*, and *Haemophilus ducreyi*.

62. (Previously Presented) The formulation of claim 1, wherein the majority of the lyophilized azithromycin is present in the form of azithromycin citrate.

63. (Previously Presented) The formulation of claim 1, wherein the majority of the lyophilized azithromycin is present in the form of sodium azithromycin citrate.

64. (Previously Presented) The pharmaceutical dosage form of claim 51, wherein the majority of the lyophilized azithromycin is present in the form of azithromycin citrate.

65. (Previously Presented) The pharmaceutical dosage form of claim 51, wherein the majority of the lyophilized azithromycin is present in the form of sodium azithromycin citrate.